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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,063	12/11/2003	Christoph Widmer	32784US5	7834
116	7590	05/19/2006	EXAMINER	
PEARNE & GORDON LLP 1801 EAST 9TH STREET SUITE 1200 CLEVELAND, OH 44114-3108			WARREN, DAVID S	
			ART UNIT	PAPER NUMBER
			2837	

DATE MAILED: 05/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/733,063

Applicant(s)

WIDMER, CHRISTOPH

Examiner

David S. Warren

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-21 and 23-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-21 and 23-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/24/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claim 21 is objected to because of the following informalities: The method claim 21 depends from an apparatus claim 1. The Examiner believes that claim 21 was intended to depend from claim 20: the rejection that follows is based on that premise. Appropriate correction is required.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 3, 4, 17 – 20, 23, 24, 27, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moro et al. (5,045,266) in view of Stanton (5,185,802). Regarding independent claims 1 and 20, Moro discloses the use of hearing device (col. 1, lines 62 – 64) and a substance provided on the surface of the hearing device (col. 3, lines 14 – 19), wherein the substance is released during predetermined time intervals (col. 3, 14 – 19). The Applicant's specification appears to define "predetermined time intervals" as long term dispatching (see specification page 40, line 10). The Examiner maintains that the "controlled release" of Moro is synonymous with Applicant's long term

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dispatching (i.e., "during predetermined time intervals"). Specifically, regarding claim 20, the claimed method steps would have been necessitated by the product structure. Moro does not disclose the use of a hearing device having an outer shell and another component, wherein the shell is adapted to a shape of an application area and wherein the shell can be exchanged from the other member remote from the individual. Stanton discloses the use of a shell (12) and removable (i.e., *exchangeable*) another component (14; fig. 2). Stanton teaches to remove and "immediately replace" the component (col. 1, lines 25 – 29), in other words, to exchange the component. It would have been obvious to one of ordinary skill in the art to combine the teachings of Moro with those of Stanton to obtain a hearing aid shell adapted to a surface of an individual for applying a substance and having an exchangeable component. The motivation for making this combination is to provide a means to maintain hygienic contact with an individual's skin over a prolonged period of time – as would be necessary with any hearing aid device. Regarding claims 3 and 23, Moro states that the substance is controllably released (col. 3, lines 16 – 19). Regarding claims 4, 17, 18 and 24, Moro discloses the use of germicides, fungicides, antibiotics, analgesics, etc. All are deemed functionally equivalent to being "antibiotically active" or "an antimicrobial agent." Regarding claim 19, migration of the medically active ingredients to the surface of the Moro hearing device shell, will provide the functional equivalent of a "film." Regarding claim 20 and new claims 27 and 28, it is inconceivable that the substance and component would be applied with the device within the individual's ear. Certainly one of ordinary skill would think to apply the substance to the shell before being inserted in the ear. Likewise for

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the component, while it may be possible to add the component with the hearing device within the ear, one of ordinary skill would find it much easier (i.e., obvious) to remove the device from the ear before exchanging the component.

4. Claim 5 – 16, 21, 25, and 26, are rejected under 35 U.S.C. 103(a) as being unpatentable over Moro et al. and Stanton as applied to claims 1, 3, 4, 17 – 20, 23, 24, 27, and 28 above, and further in view of Zaffaroni (3,996,934). The teachings of Moro and Stanton have been discussed supra. Regarding claims 5, 11 and 12, Moro and Stanton do not disclose the use of a rough surface. Zaffaroni discloses the use of a porous surface, wherein any porous surface will have a degree of roughness (col. 4, lines 51 – 57). The Examiner notes that the porous structure of Zaffaroni applies to both a covering membrane and the matrix (which is impregnated with the medically active ingredient). Regarding claims 6, 8, and 10, both Moro and Zaffaroni disclose placing material within the matrix (or shell) – as defined by Applicant, this will constitute a film. Regarding claim 7, the Examiner maintains that all substances have structure, e.g., molecular structure, polymeric structure, etc. Regarding claim 9, Zaffaroni discloses matrix dimensions of 50 angstroms (or less) to 100 microns, a matrix of 50 angstroms will deliver a substance of 50 angstroms or less, certainly 50 angstroms can be fairly interpreted as a “micro-structure.” Regarding claim 13, (“slow” is a relative term) both Moro and Zaffaroni disclose slow release (e.g., see Zaffaroni, col. 12, last sentence). Regarding claims 14 – 16, Zaffaroni does not specifically disclose the use of

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a liquid, gel, and/or paste, but instead states "the viscosity" (col. 4, lines 57 – 64) may be chosen in accordance with the matrix pore size. The Examiner maintains that this is functionally equivalent to using structures, micro-structures, with a liquid, gel, and/or paste. In other words, the viscosity (i.e., liquid, gel, or paste) may be varied in accordance with pore size to achieve a desired active ingredient release rate – which is vital in administering medicaments. The limitations of claim 21 (see the objection to claim 21, discussed supra) are discussed supra with regard to claims 5 – 9. Regarding new claims 25 and 26, as stated supra, it is inconceivable that the substance and component would be applied with the hearing device within the individual's ear. Certainly one of ordinary skill would think to apply the substance to the shell before being inserting the device in the ear. Likewise for the component, while it may be possible to exchange the component with the hearing device within the ear, one of ordinary skill would find it much easier (i.e., obvious) to remove the device from the ear before exchanging the component. It would have been obvious to one of ordinary skill in the art to combine the teachings of Moro and Stanton with those of Zaffaroni to obtain a hearing device with a substance applied thereto, wherein the shell provides a matrix for the substance. The motivation for making this combination is improved transdermal drug delivery.

Response to Arguments

5. Applicant's arguments with respect to claims 1, 3, 4, 17 – 20, 23, 24, 27, and 28 have been considered but are not persuasive. The Applicant states that “[t]he mere fact that the references can be combined or modified does not render the resultant combination obvious, unless the prior art also suggests the desirability of the combination.” The Applicant is reminded that the MPEP states that “the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference.... Rather, the test is what the combined teachings of those references would have suggested to those of ordinary skill in the art” [emphasis added]. The Applicant is referred to MPEP 2145 (III). The Examiner maintains that the Moro and Stanton references would have suggested Applicant's invention to one of ordinary skill (as outlined in the rejection above). The Applicant also argues that “[a]t best, one of ordinary skill in the art would be motivated to regularly clean or replace either Moro's or Stanton's respective hearing aid and shell, in order to maintain hygienic contact with an individual's skin.” The Examiner fails to understand why one of ordinary skill would be motivated to clean and replace the shell when Moro explicitly states the use of a “controlled release of medicinally active substances, i.e., such as germicides, fungicides, antibiotics, analgesics, etc.” Regarding claims 5 – 16, 21, 25, and 26, the Applicant argues that the Examiner's motivation to combine the references is based on inappropriate hindsight. In response to applicant's argument that the examiner's conclusion of obviousness is based upon

improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

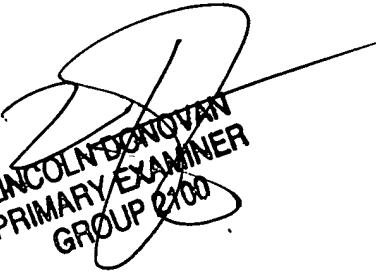
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David S. Warren whose telephone number is 571-272-2076. The examiner can normally be reached on M-F, 9:30 A.M. to 6:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lincoln Donovan can be reached 571-272-1988. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

dsw


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